NDA 20-375/S-013

MAY 2 0 1999

Berlex Laboratories, Inc.
Attention: Mr. Geoffrey Millington
Manager, Drug Regulatory Affairs
340 Changebridge Road
P. 0. Box 1000
Montville, NJ 07045- 1000

Dear Mr. Millington:

Please refer to your supplemental new drug application dated January 19, 1999, received January 22, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Climara®, (estradiol transdermal system) 0.025, 0.05, 0.075 and 0.1 mg/day.

We acknowledge receipt of your amendment dated May 5, 1999.

This supplemental new drug application provides for revising the current labeling and associated analytical methods and specifications to reflect clarification of the use of estradiol as the anhydrous form.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted draft labeling (package insert and immediate container and carton labels submitted May 5, 1999). Accordingly, the supplemental application is approved effective on the date of this letter.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-375/S-013/S-013." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR314.80and314.81.

If you have any questions, contact Ms. Diane Moore, Regulatory Project Manager, at (301) 827-4260.

Sincerely,

5/20/99

Lisa D. Rarick, M.D.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research